Meetings With Industry

CBER 101

March 2004

What You Need to Know About Meetings with Sponsors

- Why should FDA meet with sponsors?
- Legal requirements regarding meetings
- How meetings with sponsors are integrated into the Managed Review Process
- Resources for conducting meetings
- Roles and responsibilities of reviewers and regulatory project managers.

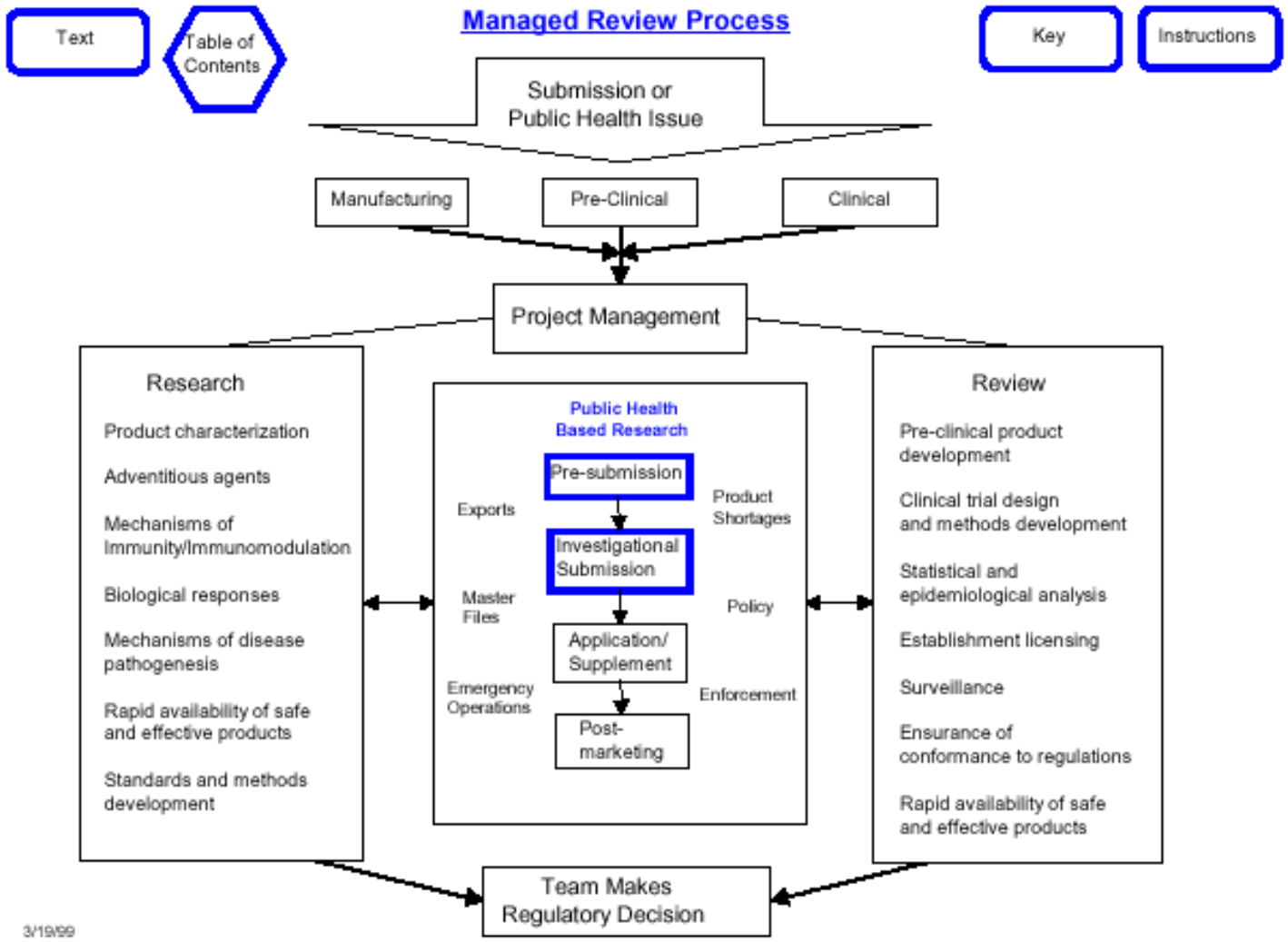
Why Should FDA Meet With Sponsors?

- 21 CFR 10.65
  - (d) states that meetings may be requested
  - (e) “FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the Agency.”

Legal Requirements

- 21 CFR 10.65
- FDAMA
  - Section 101: Meeting Management goals (User Fee Products) (Letters to Subcommittees)
  - Section 201/205: Early Collaboration Procedures (Medical Devices, IDE/PMA)

How meetings with sponsors are integrated into the Managed Review Process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Types of Meetings

- Pre-Submission
- Investigational Submission
- Application Submission
- Post Marketing

"Cradle to Grave"

Resources for Conducting Meetings

- Law: FDAMA and associated “letters”.
- Regulations: 21 CFR 10.65
- SOPPs: 8101.1, CRMTS
- Guidance
  - CBER
  - CDRH

Guidance On Meetings

- CBER
  - Formal Meetings with Sponsors and Applicants for PDUFA Products (February 2000)
  - Formal Meetings with CBER or CDER Regarding non-PDUFA Products or Issues Unconnected with an Application (DRAFT)

Guidance On Meetings

- CDRH
  - Early Collaboration Meetings Under FDA Modernization Act (FDAMA), Guidance for Industry and CDRH Staff (28 Feb 01)
  - Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies - for Use by CDRH and Industry (19 Feb 98)

Please Bear in Mind

Agency policy development should not be part of a sponsor meeting

Roles and Responsibilities of RPMs

- Application Divisions (RPMs)
  - Ensure SOPP 8101.1 followed by team/sponsor
  - Update meeting database (CRMTS)
  - Schedule internal pre-meeting to discuss meeting materials (as per MRP)
  - Handle meeting logistics (Room, phone, AV, etc.)
  - Ensure team issues meeting minutes by day 30

Roles and Responsibilities of Reviewers

- Laboratory (Review) Divisions:
  - Assign scientific lead
  - Have disciplines represented
  - Resolve issues at internal pre-meeting
  - Provide notes/backup to RPM
  - Edit minutes and forward to RPM on-time

Successful Meetings

- Encourage the sponsor to provide questions in the pre-meeting package (not open-ended)
- Be clear on who on the FDA review team owns which discipline/issue.
- Do your homework on your discipline on time; if you can't get it done, tell your supervisor. Don't wait!

Successful Meetings

- Have an internal pre-meeting several days before the sponsor meeting to discuss issues and allow time to resolve complex issues.
- Stick to the agenda and time!
- New issues may legitimately arise during the meeting; limit new issue discussion and revisit as appropriate

Successful Meetings

- If a controversy arises, caucus (strategize) briefly in private
- Enroll in Project Management/Meeting training to learn how your role impacts the organization